IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/692,031
Confirmation No.:	5358
First-Named Inventor:	William F. Crismore
Filing Date:	October 23, 2003
Group Art Unit:	1797
Examiner:	Alexander, Lyle
Attorney Docket No.:	007404-000571
Title:	ELECTROCHEMICAL BIOSENSOR TEST STRIP

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Answer dated March 19, 2010, in connection with the above-indicated application, a Reply Brief according to 37 CFR §41.41 is provided.

The Commissioner is authorized to grant any further extensions of time and charge any deficiency or credit any overpayment to Deposit Account No. 23-3030 but not to include issue fees.

TABLE OF CONTENTS

I. STATUS OF CLAIMS

(37 CFR §41.37(c)(1)(iii))

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are 68-104.

B. STATUS OF ALL THE CLAIMS

1. Claims canceled: 1-67.
2. Claims withdrawn from consideration but not canceled: None.
3. Claims allowed: None.
4. Claims rejected: 68-104.
5. Claims objected to: none.

C. CLAIMS ON APPEAL

The claims on appeal are 68-104.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(37 CFR § 41.37(c)(1)(vi))

The March 19, 2010, Examiner's Answer, withdrew the Double Patenting Rejections and all of the 35 U.S.C. § 102 rejections from the March 9, 2009, Office Action. Therefore, the following grounds of rejection are presented for review by the Board.

A. Claims 68-104 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

B. Claims 68-104 stand rejected under 35 U.S.C. § 251 as being based upon new matter added to the patent for which reissue is sought.

III. ARGUMENT

(37 CFR § 41.37(c)(1)(vii))

The contentions of the applicant and the basis for those contentions with respect to each ground of rejection is presented below.

A. Rejections Under 35 U.S.C. § 112, First Paragraph

1. Independent Claims 68, 82, and 96

The March 19, 2010, Examiner's Answer, asserts "The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification, as described in USP 5,997,817, does not teach a "fill line" to determine addition of the proper amount of sample."

The March 19, 2010, Examiner's Answer, also asserts "Appellants quote excerpts from the original specification on pages 22-23 of the Brief they believe support the contested language "a fill line". The Office notes the common features of these excerpts are "…a transparent or translucent window **which operates** as a 'fill to here' line…" and "…roof 13 includes transparent or translucent window 18…" The Office has read these excerpts and the original specification as teaching the test strip has a transparent cover. These cited excerpts and the original specification do not teach or suggest placement of an actual "fill line" as presently claimed."

In traversal, the Applicants stand behind and reassert all of the explanations and arguments that are set forth in the Appeal Brief. Nothing the Examiner has stated in the Examiner's Answer changes or lessens the effect and strength of those earlier explanations and arguments. First, Applicants assert the March 19, 2010, Examiner's Answer fails to address the

additional support for the "fill line" provided on page 24 of the Appeal Brief. Second, Applicants assert the March 19, 2010, Examiner's Answer mischaracterizes the disclosure of the "fill line" provided on pages 21, 22, and 23 of the Appeal Brief.

Support for "fill line"

Independent Claims 68, 82, and 96 include "a fill line extending across the capillary channel (viewing area) at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test." General support for the claims, including the provision of a "fill line", is found throughout the specification and the drawings and is repeated below as well as on pages 21 and 22 of the Appeal Brief.

Abstract, lines 11-15:
"The roof of the capillary test chamber includes **a transparent or translucent window which operates as a *'fill to here' line***, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." (emphasis added)

Col. 1, line 61 to Col. 2, line 5:
"The second new feature is a transparent or translucent window which operates as ***a 'fill to here' line***, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test. **The window defines the minimum sample amount, or dose, required to accurately perform a test**, and, therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip. (emphasis added)

Col. 2, lines 6-14:
The window is dimensioned and positioned so that it overlays the entire width of the working electrode and at least about 10% of the width of the counter or reference electrode of the biosensor test strip. **Preferably, the area of the roof surrounding the window is colored in a way that provides good color contrast between the sample, as observed through the window, and the roof area surrounding the window for ease of identifying sufficient dosing of the strip**." (emphasis added)

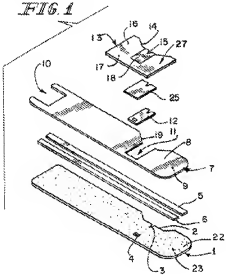
Col. 4, lines 36-41:
"**Preferably, roof 13 further includes transparent or translucent window 18**. Window 18 is dimensioned and positioned so that when roof 13 is affixed to second insulating

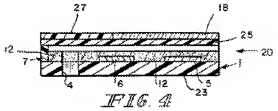
substrate 7, the window overlays the entire width of conductive track 5 and at least about ten percent of the width of conductive track 6." (emphasis added)

Col. 8, lines 27-32:
"A substantially **opaque** ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent." (emphasis added)

Col. 8, lines 53-55:
"Finally, roof 13 is placed onto surface 8. (See FIG. 3h) It is at this stage that the **transparent or translucent window 18 defined by the absence of printed ink on roof 13** must align with opening 11 as shown in FIG. 3h." (emphasis added)

As illustrated in FIG. 1, roof (13) includes transparent or translucent window (18). Window (18) is demarcated with a pair of opposing sidelines, a sample receiving edge that may include notch (15), and a "fill line" that is opposite the sample receiving edge.





The "fill line" is represented in FIG. 4 as the vertical line separating window (18) and pattern (27) on roof (13). As the body fluid sample reaches the "fill line" on window (18), the user can visually identify a sufficient filling of the test strip or biosensor for conducting a test.

The cited excerpts and original specification disclose the "fill line" is formed on roof (13) by at least two techniques. The first technique includes printing or placing a substantially opaque ink on first surface (16) of roof (13) to form pattern (27) such that window (18) remains

transparent or translucent. As illustrated in FIGS. 1 and 4, the "fill line" is produced by the interface of the opaque ink that forms pattern (27) printed on first surface (16) of roof (13) and the translucent or transparent window (18) formed by the absence of opaque ink on the roof (13). Pattern (27) forms a perimeter around window (18) such that a line of demarcation occurs between the portion of the roof (13) that is covered with substantially opaque ink, i.e., pattern (27), and the portion of the roof (13) that remains transparent or translucent, i.e., window (18). The "fill line" is the portion of the perimeter opposite the sample receiving edge such that movement of the blood sample from the sample application port (20) to the "fill line" indicates sufficient filling of the test strip for conducting a test.

The second technique includes coloring the area of the roof (13) surrounding the window (18) in a way that provides good color contrast between the sample, as observed through the window, and the roof area surrounding the window for ease of identifying sufficient dosing of the strip. A line of demarcation occurs between the portion of the roof (13) that is colored and the transparent or translucent window (18). The colored portion of the roof (13) could also be transparent or translucent. The "fill line" is the portion of the perimeter opposite the sample receiving edge such that movement of the blood sample from the sample application port (20) to the "fill line" indicates sufficient filling of the test strip for conducting a test.

In either embodiment, window (18) defines the minimum sample amount, or dose, required to accurately perform a test. In other words, if the sample has colored and/or filled the window (18) to the "fill line" then the sample amount is enough to accurately perform a test. Hence, window (18) and the "fill line" represent a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip.

Mischaracterization of the Written Disclosure

As stated above, the March 19, 2010, Examiner's Answer, also asserts "Appellants quote excerpts from the original specification on pages 22-23 of the Brief they believe support the contested language "a fill line". The Office notes the common features of these excerpts are "...a transparent or translucent window **which operates** as a 'fill to here' line..." and "...roof 13 includes transparent or translucent window 18..." The Office has read these excerpts and the original specification as teaching the test strip has a transparent cover. These cited excerpts and the original specification do not teach or suggest placement of an actual "fill line" as presently claimed."

Applicants assert these statements misconstrue the disclosure and the claims. Applicants disclose and teach that a substantially opaque ink is applied to the area of the roof (13) surrounding the window (18) such that the window defines the minimum sample amount, or dose, required to accurately perform a test. Thus, there is a "fill line" that is applied to the test strip by way of the intersection of the transparent or translucent window (18) and the substantially opaque ink that forms pattern (27).

In one embodiment illustrated in FIG. 3i, the "fill line" is a horizontal line that is positioned about midway between notch (15) and the rear of the capillary chamber which is located at the edge of the test strip opposite the notch (15). In FIG. 3i, the "fill line" is shown near the end of the leader line from reference number 18 that points to window (18).

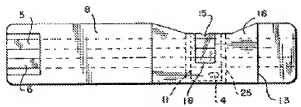


FIG. 3i

Applicants submit the application as originally filed sufficiently discloses the concept claimed herein, that being the provision of a "fill line" or a line demarcated on a test strip which indicates to where the body fluid or blood sample must fill in order to conduct a test.

B. Rejections Under 35 U.S.C. § 251

1. Independent Claims 68, 82, and 96

The March 19, 2010, Examiner's Answer, asserts "The original specification, as described in USP 5,997,817, does not teach a "fill line" to determine addition of the proper amount of sample."

In traversal, the Applicants submit that for the reasons stated above and in the Appeal Brief, the original specification described in USP 5,997,817 does teach a "fill line" to determine the proper amount of sample.

IV. CONCLUSION

For the above reasons, the rejections of claims 68-104 under 35 U.S.C. §112, first paragraph, and 35 U.S.C. § 251 are in error and should be reversed. Applicants thus respectfully request reversal of the present rejections and passage of the present application to issuance.

Respectfully submitted,

By / Elizabeth A. Shuster, #52,672 /
Elizabeth A. Shuster, Reg. No. 52,672
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
Telephone: (317) 634-3456 Fax: (317) 637-7561
Email: eashuster@uspatent.com